Formulation of a multivariate predictive model for difficult intubation: A double blinded prospective study

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Abstract

Background and Aims: Various models were devised for prediction of difficult intubation but have low positive predictive value, sensitivity and specificity. We aimed to predict difficult intubation from various airway predictive indices, in isolation and combination, and to formulate a multivariate model that can aid in accurate prediction of difficult intubation.

Material and Methods: A prospective double blinded study was conducted on 500 adult patients scheduled for elective surgery under general anaesthesia. Preoperatively, they were assessed for airway screening tests. After standardized induction of anaesthesia, laryngoscopic view was classified according to the Modified Cormack and Lehane (MCL) classification. Variables' association with intubation findings was evaluated using Chi-square statistic. Stepwise logistic regression identified the multivariate independent predictors of difficult intubation and combinations were made using forward selection process. 8 models were formulated and a receiver-operating characteristic (ROC) curve worked out for them. Sensitivity and specificity analysis validated the final model.

Results: Age, sex, weight, BMI, snoring, obstructive sleep apnea (OSA), diabetes, hypertension, upper lip bite test (ULBT), Mallampati grade (MPS), thyromental distance (TMD), sternomental distance (SMD), neck movements (NM), neck circumference (NC) and inter-incisor gap (IIG) had significant correlation with difficult intubation. Based upon sensitivity and specificity analysis, model comprising of MPS, NM, NC and SMD was found to be most accurate. It had highest sensitivity 80%, specificity 87% and area under curve 0.90, thus validating the model.

Conclusions: Our study found that a combination of MPS, SMD, NM and NC permits reliable, accurate and quick preoperative prediction of difficult intubation.

Keywords: Airway assessment, difficult intubation, predictive tests, upper lip bite test

Introduction

Airway mishaps are always an issue of concern, and accounts for frequent and major financial medical claims.[1,2] Prediction of difficult airway has been studied vastly but yet without near ideal prediction model with high reliability and validity. Various models have been devised for prediction of difficult intubation but have low positive predictive value, sensitivity and specificity.[3-6]

Our study aimed to determine the factors, in isolation and combination to predict difficult intubation and to formulate a model from various pre-operative indices which included airway screening tests/variables and demographic profile of the patients that can aid in accurate prediction of difficult intubation.

Material and Methods

After approval from Institutional Ethics Committee (IEC) and written informed consent from the patients, this double

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blinded prospective study was conducted on 500 adult ASA grade 1and 2 patients, aged more than 18 years of either sex, scheduled for elective surgery under general anaesthesia. Patients having gross anatomical/congenital abnormalities of head and neck or unstable cervical spine, unable to sit or stand erect, with severe cardio respiratory disorders, pregnant and edentulous patients were excluded from the study. Double blind technique was employed by blinding the investigator doing laryngoscopy about the pre-operative airway assessment. A single investigator performed preoperative assessments of all patients and did not participate in the care of anaesthesia to the patients.

Preoperatively, demographic information (age, sex, weight, height, BMI) of the patient, history of any medical condition that might affect airway [Diabetes Mellitis (DM), Rheumatoid Arthritis, Scleroderma, etc] and history of difficult intubation in past were noted. Patient's airway was assessed for the following tests.

Dentition was described as presence of normal, moderate and severe buck teeth. This was a subjective assessment based on a series of photographs.[7]

Mouth Opening (Inter-Incisor Gap: IIG) was recorded as the distance between the upper and lower incisors with the mouth fully open.[4] It was evaluated as: IIG <3.5 cm, 3.5-5 cm and >5 cm.

Upper lip bite test (ULBT) proposed by Khan *et al*.[8] was performed by asking the patient to bite the upper lip as far as possible with the lower incisors. The observations were graded as follows:

Class I: Lower incisors could bite the upper lip above the vermilion line.
Class II: Lower incisors could bite the upper lip below the vermilion line.
Class III: Lower incisors could not bite the upper lip.

The airway was then classified according to the Modified Mallampati scale (MPS)[9] with the patient sitting upright, head in the neutral position, mouth wide open and tongue protruded out.

Class 1- soft palate, fauces, uvula, pillars visible.
Class 2- soft palate, fauces, uvula visible.
Class 3- soft palate, base of uvula visible.
Class 4- soft palate not visible at all.

Thyromental distance (TMD) was measured along a straight line from thyroid notch to the lower border of the mandibular mentum with the head fully extended and categorised as: >6.5 cm, 6.0-6.5 cm and <6.0 cm.[10]

Sternomental distance (SMD) was measured as straight distance between the upper border of the manubrium sternii and the bony point of the mentum with the head fully extended and mouth closed.[11] It was described as: >12.5 and <12.5 cm.

Head-neck movements (NM)[7] was described as: >90 degree, 80-90 degree and <80 degree. The patient was asked to extend fully the head and neck while a pencil was placed vertically on the forehead. The orientation of the pencil was adjusted so that it was parallel to a distant window frame. Then, while the pencil was held firmly in position, the head and neck were flexed and the pencil was sighted against the horizontal of the window frame to judge if it had moved through 90^0.

Neck circumference (NC) was measured in centimetres at the level of thyroid cartilage.[12]

All patients were kept fasting at least 6 hours before surgery. They were premedicated with Tab. Ranitidine 150 mg and Tab. Diazepam 5mg at night and at 6 am on morning of surgery. After keeping difficult intubation cart and all resuscitative measures ready, patient was positioned supine on operating table and standard monitoring [pulse oximetry (SpO_2), heart rate (HR), electrocardiography (ECG), non-invasive blood pressure (NIBP) and end tidal capnography ($EtCO_2$)] was instituted. Following preoxygenation for 3 minutes, patient was induced with 2 μg/kg Fentanyl, 3-5 mg/kg of Thiopentone sodium 2.5% titrated to abolition of eyelash reflex and Succinylcholine 1.5 mg/kg to facilitate endotracheal intubation. With patient's head in sniff in morning air position, laryngoscopy was performed using a Macintosh blade number 3 by the anaesthesiologist (of at least 3 years post MD experience) who was blinded to preoperative airway assessment. The laryngoscopic view with or without optimal external laryngeal manipulation was classified using the Modified Cormack and Lehane's (MCL) classification: grade 1 where entire vocal cords were visible, grade 2a where a part of vocal cords were visible, grade 2b where only arytenoids or the very posterior origin of cords were visible, grade 3 where only epiglottis was visible and grade 4 where no glottic structure was visible. After evaluation, tracheal intubation was done with endotracheal cuffed tube of appropriate size and confirmed with capnography. Number of attempts and special maneuvres or airway devices used were noted. Laryngoscopy and endotracheal intubation was considered difficult if MCL grades 2b, 3 or 4, more than 3 multiple attempts were required at tracheal intubation;

special devices such as stylet, bougie, intubating LMA or videolaryngoscope; or multiple laryngoscopists were used to facilitate tracheal intubation.

The association of the individual variable with intubation findings was evaluated using Chi-square statistic and percentage contribution to intubation difficulty using z-test. $P < 0.01$ was regarded as significant. Sensitivity, specificity, positive and negative predictive value analyses were done for each variable. Stepwise logistic regression analysis, using the SPSS program, version 11.0, identified the multivariate independent predictors of difficult intubation and combinations were made using forward selection process. 8 models were formulated and a receiver-operating characteristic (ROC) curve worked out for them. Sensitivity and specificity analysis finally validated the new model.

Results

This study was conducted on 500 adult patients, out of which 223 were males and 277 females. The mean age was 52 years with standard deviation of 10.67, average height was 159 cm (145-180) and average weight 77kg (35-120kg). In our study, the incidence of difficult intubation was found to be 8.8% (when CL grade III was used as end point) and 29% (when CL grade 2b, use of external laryngeal pressure or use of any other special instrument for intubation were used as end point for difficult intubation). There was no failure to intubate the trachea in our study.

Statistically significant association ($P < 0.001$) of difficult intubation was found with age, weight, BMI, history of snoring, obstructive sleep apnea (OSA), history of DM and HT, ULBT, TMD, SMD, IIG, NM and NC [Table 1]. In contrast, gender, height and past history of co-morbid conditions other than diabetes did not gain any statistical significance. Sensitivity, specificity, predictive values and P values of various factors in determining the difficulty in intubation are shown in Table 2. Highest sensitivity was observed with inter-incisor gap (<5cm) followed by BMI (>35kg/sqm). MPS has highest specificity followed by thyromental distance followed by history of snoring. Overall predictive values (OPV) were highest for Mallampati score followed by thyromental distance.

Multivariate analysis i.e. regression analysis of fourteen variables of our study was done in order to know the factors that determine the type of intubation. Regression co-efficient, t-values, P values and 95% confidence intervals were worked out. We found that OSA, buck teeth, MPS, TMD, SMD,

Table 1: Association of various factors with difficult intubation

Parameter	Difficult Intubation (CL grade 2b, 3 & 4) *N*=145 (29%)	Easy Intubation (CL grade 1, 2a) *N*=355 (71%)	*P*
Age (>45 yrs)	108 (74.5)	157 (44.22)	<0.001
Gender (F)	90 (62)	187 (52.67)	<0.07
Height (155-165 cm)	56 (38.62)	171 (48.17)	0.04
BMI (>35kg/m^2)	121 (83.44)	126 (35.5)	<0.001
Snoring (Y)	63 (56.55)	32 (9.01)	<0.001
ULB (>1)	94 (64.82)	61 (17.2)	<0.001
Buck teeth (>mild)	91 (62.75)	60 (17)	<0.001
MPS (>II)	65 (44.83)	0 (0)	<0.001
TMD(<6.5 cm)	62 (42.76)	2 (0.56)	<0.001
SMD (≤12.5 cm)	100 (69)	126 (35.5)	<0.001
NM(≤90D)	101 (70)	120 (33.8)	<0.001
History (HT + DM)	53 (36.55)	10 (2.82)	<0.001
History (HT)	41 (28.28)	70 (19.72)	0.047
History (DM)	5 (3.45)	4 (1.13)	0.093
IIG(<5 cm)	1 (0.69)	4 (1.13)	<0.001
NC (>35 cm)	124 (85.5)	147 (41.4)	<0.001
OSA (Y)	13 (8.97)	0 (0)	<0.001

Table 2: Predictive values of various factors in predicting difficult intubation

Parameter	Sensitivity	Specificity	PPV	NPV	OPV
Age (>45 yrs)	74.48	55.77	40.75	84.26	61.20
Gender (F)	62.07	47.32	32.49	75.34	51.60
BMI (>35kg/m^2)	90.34	64.51	50.97	94.24	72.00
Snoring	56.55	90.99	71.93	83.68	81.00
ULB (>1)	64.83	82.82	60.65	85.22	77.60
Buck teeth (>Mild)	62.76	83.10	60.26	84.53	77.20
MPS (>II)	44.83	100	100	81.61	84.00
TMD(<6.5 cm)	42.76	99.44	96.88	80.96	83.00
SMD (≤12.5 cm)	68.97	64.51	44.25	83.58	65.80
NM(≤90D)	69.66	66.20	45.70	84.23	67.20
History (Y)	71.72	73.80	52.79	86.47	73.20
IIG(<5 cm)	99.31	1.13	29.09	80.00	29.60
NC (>35 cm)	85.52	58.59	45.76	90.83	66.40

NM and NC had statistically significant p- value. Other factors i.e., BMI, snoring, ULBT had $P > 0.05$. Age, sex, weight and height were seen to be non significant in the final run equation. Step wise elimination was done for each variable in order to reach a model that had highest statistical significance.

The percentage contribution made to prediction of difficult intubation by variables taken was calculated individually and in combination. It was observed that maximum contribution was made by combination of ULBT, MPS, SMD, NM and NC. However, it was observed that if ULBT was eliminated from this combination, there was no significant decrease in the percentage contribution of the combination. Therefore, a model consisting of four variables i.e., MPS, SMD, NM and NC was built and it was validated on the study population by sensitivity and specificity analysis that is shown in Table 3.

We found that our first model i.e. the combination of MPS, NM and NC had highest OPV. If SMD was added to this combination the model had highest sensitivity and specificity but the positive predictive value (PPV) was less than first model that decreased the OPV. Addition of ULBT not only decreased OPV due to decrease in PPV but also decreased sensitivity and specificity. Hence this test was not included in the final model. So, finally on basis of multivariate analysis we formulated a model comprising of MPS, SMD, NM and NC and its validity analysis proved that it has highest sensitivity 80% and specificity 87%. Overall ROC for this model was very powerful with area under curve (AUC) of 0.90.

Discussion

Unanticipated difficult airway is a challenging task and is a major source of any apprehension to anaesthesiologist as it may result in poor outcome. Airway mishaps accounts for frequent and major medical claims against anaesthesiologists because of the nature of their outcome.[1,2] Prediction of difficult airway has been always an issue of debate and concern. Various models have been devised for prediction of difficult intubation but most of these are proven to be inaccurate and far from near ideal.[3-6]

In our study, the incidence of difficult intubation was found to be 8.8% using CL grade III alone as end point, which was comparable to incidence reported by Cohen *et al*. (7.22%),[13] Rose and Cohen (10.1%)[14] but was lower than that of Mallampati (13.3%)[9] and Eberhart *et al*. (12%).[15] Prakash *et al*.[16] found similar incidence (9.7%) in Indian population. However, with CL grade IIb as end point for difficult intubation, the incidence of difficult intubation increased to 29% in our study. There was no failure to intubate the trachea in our study.

We considered following parameters for prediction of difficult intubation i.e. age, sex, height, weight, BMI, history of snoring, OSA, history of medical illness, IIG, ULBT, buck teeth, MPS, TMD, SMD, NM and NC on the basis of previous studies in literature.[7-12] In our results, it was observed that group of patients with history of DM along with HTN had a statistically significant relationship with difficult intubation. These observations were comparable to results of Reissel *et al*. who have concluded that history of DM can lead to intubation difficulties due to stiffness of neck joints restricting their movements.[17] There was no significant difference in the sex ratio of patients in the two groups of easy and difficult intubation. The results of our study were comparable to that of Wilson[7] and Savva[11] for gender. We found that overweight and increase in age were risk factors for difficult intubation as reported in earlier studies too.[14]

On univariate analysis, MPS, TMD, history of snoring and ULBT had highest OPV as compared to other variables i.e. 84%, 83%, 81% and 77% respectively. Sensitivity of Modified Mallampati test alone in the present study (45%) is less than that of Freck (56%),[18] Savva (64.7%),[11] Butler (56%)[19] and is comparable to that of Oates (42% to 50%).[20] The PPV in various studies show a wide variation ranging from 93% for Mallampati[9] to 8.9% for Savva[11] while the present study had 100% heterogeneity and inadequate diagnostic performance may result in part from inconsistency or uncertainty in performing the test.[21] When used alone, Mallampati test is insufficient to predict the difficult airway with accuracy.

ULBT was found to have sensitivity of 64% and specificity of 83% that was lower to the original study done by Khan *et al*. (sensitivity 76% and specificity 88%)[8] but sensitivity was higher and specificity was lower than the study conducted by Eberhart *et al*.[15] in which these were 28% and 92.5% respectively. The difference in sensitivities may be due to difference in number of patients (1425) included in Eberhart study as compared to Khan's study (300) and our study (500). It may also be due to higher incidence of difficult intubation in our population (8.8%) as compared to Khan's study (5.7%).

Table 3: Predictive values of various proposed models in predicting difficult intubation

Models	Senstivity	Specificity	Ppv	Npv	Opv	Rank
ULB +MPS +SMD +NM +NC	77.2	84.1	53.7	86.1	67.4	IV
ULB +MPS +SMD +NM	75.3	81.6	51.6	83.9	65.2	VI
ULB +MPS +SMD	71.4	77.6	48.6	76.9	60.5	VIl
MPS +NM +NC +SMD	79.7	87.1	56.8	89.5	71.2	II
MPS +SMD +NM	71.7	82.5	51.2	84.6	65.3	V
MPS +SMD +NC	74.2	79.6	60.5	83.1	69.3	III
SMD +NM +NC	70.5	53.2	51.5	71.9	59.4	VII
MPS +NM +NC	75.4	81.9	62.4	86.5	72.7	I

Neck circumference had a sensitivity of 88.5% in our study that was comparable to the observations by Gonzalez *et al.*[22] where the sensitivity was 92% thereby concluding that neck circumference should be assessed preoperatively to predict a potentially difficult intubation. Our results also confirm the results of Brodsky *et al.*[12] who showed that neck circumference at the thyroid cartilage is a valuable predictor of difficult laryngoscopy in obese patients.

We found that history of snoring had significant association with difficult intubation with overall predictive value of 81% which was comparable to findings of study by Hiremath *et al.*[23]

As the individual parameters have low accuracy, to improve PPV a combination of predictive variables can be used to build a model so as to predict patients with difficult intubation preoperatively with greater accuracy. An ideal model for prediction of difficult intubation would have perfect specificity and sensitivity. It is important to detect as many patients with difficult airway as possible to minimize the potentially serious consequences of unanticipated difficult tracheal intubation. Hence a model with high sensitivity, rather than high specificity is required.[6] We developed a clinical prediction model using logistic regression analysis that includes four airway screening tests: MPS, SMD, NM and NC. Our model has sensitivity of 80% and specificity of 87%. Sensitivities and specificities for Wilson's model were 75% and 88%,[7] 59.8% and 94% for El- Ganzouri's model,[4] 81.4% and 72.2% for Naguib[5] model, 94% and 96% for Arne[6] model and 86.8% and 96% for Karkouti[3] model. The Ganzouri's[4] model had very low sensitivity, thereby will miss many patients with difficult intubation.

Naguib's model had a high sensitivity and specificity but it included radiological parameters like X ray and 3D CT.[24] These procedures are difficult to perform and are time consuming. In another study, where Naguib *et al.* compared different models and developed a new clinical prediction model, was a matched case controlled study, hence some segments of population may not be adequately represented in the study participants. Moreover, it was not a truly prospective study which could bias the results.[5]

Arne's[6] model consisted of seven criteria with each having a scoring system for the prediction of difficult intubation. This scoring system is time consuming and thus, has limited role in routine quick evaluation.[6] In comparison to these complex scoring systems like the Wilson's risk sum score,[7] our proposed model also has an advantage of being simple to allow clinical use and is less time consuming.

Karkouti *et al.*[3] formulated a model with accuracy but with low PPV as there was no standardisation of both the anaesthesia technique and the experience of the anaesthesiologist performing laryngoscopy. In addition to this, there was inclusion of patients with difficult intubation who were not assessed pre-operatively. The inclusion of this group could bias the results as the assessor was aware of the intubation information at the time of airway assessment. This bias was removed by double blinding in our prospective study in which standardised methodology was adhered to strictly.

The variation in predictive values of different models is probably because of difference in geographical areas having its impact on different anatomical facial features. The accuracy of model may vary in routine clinical practice when used by anaesthesiologists of variable experience or when different induction techniques are used. Validation analysis of our model suggests that it will perform well in other similarly defined patient populations as long as the variables are measured accurately.

Most of earlier models have not studied ULBT test in combination with other variables. We aimed to incorporate this test and study its validation for prediction of difficult intubation. Percentage contribution to difficult intubation of our model did not improve significantly by addition of ULBT; rather a decrease in sensitivity and specificity occurred. Hence, it was not included in the final model. ULBT is a qualitative test in which class 1 has easy intubation whereas as we progress to higher grading, intubation becomes difficult. Thus, ULBT when used singly is an accurate predictor of difficult intubation and its combination with other tests may give variable results such as decrease in sensitivity and specificity, probably due to anatomical differences in the races. However few studies done in combinations with ULBT have reported variable results. Recently, Wajekar AS (2015) *et al.*[25] studied various combinations to predict difficult intubation in 402 patients. Authors reported that although ULBT is not a suitable predictive test for difficult intubation when used alone, however when combined with MMT and TMD, produced highest specificity (56.5%) with an acceptable sensitivity (80.3%), NPV in lower range (27.1%) and PPV in same range (93.5%) as other tests. In another recent study, Honarmand compared various difficult airway predictors and concluded that ratio of height to thyromental distance (RHTMD) and ULBT tests have a higher level of accuracy compared to NC/TMD, NC and MMT in predicting a difficult airway.[26] Shah *et al.* also found that ULBT and RHTMD had highest sensitivity, specificity, PPV, NPV and likelihood ratio compared to TMD, MMT, IIG and NM.[27] However, we have not studied RHTMD as a predictor for difficult intubation.

The limitation of this study was that cohort was relatively small to predict difficult intubation. Validation (prospective testing) of this proposed combination of predictive tests was not performed. A multicentric study including a larger number of patients could be done to increase the power of the study and validate our model.

Hence, to conclude, we propose the use of a simple model (a combination of Mallampati score, sternomental distance, neck movements and neck circumference) which permits reliable, accurate and quick preoperative prediction of difficult intubation. Application of this model for preoperative prediction can reduce the frequency of both unanticipated failure to visualise laryngeal structures as well as potentially unnecessary interventions related to over-prediction of airway difficulty. It remains essential for optimal outcome that the anaesthesiologists understands the limitations of all the predictive models and remain prepared to follow appropriate algorithms with adequate back up facilities to avoid serious complications of unanticipated difficult intubation.

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Conflicts of interest

There are no conflicts of interest.

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